A/RE

Please type a plus sign (+) inside this box → [+]

PTO/SB/50 (4/98)
Approved for use through 09/30/2000. OMB 0651-0033
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REISSUE PATENT APPLICATION TRANSMITTAL

Address to:
Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

Attorney Docket No.	(B&B) TRI 42
First Named Inventor	Baumann
Original Patent Number	5,667,504
Original Patent Issue Date (Month/Day/Year)	Sept. 16, 1997
Express Mail Label No.	

APPLICATION FOR REISSUE OF: *(check applicable box)* [X] *Utility Patent* [ ] *Design Patent* [ ] *Plant Patent*

APPLICATION ELEMENTS

1. [X] * Fee Transmittal Form *(PTO/SB/56)* *(Submit an original, and a duplicate for fee processing)*
2. [X] Specification and Claims (*amended, if appropriate*)
3. [X] Drawing(s) *(proposed amendments, if appropriate)*
4. [X] Reissue Oath / Declaration (original or copy) *(37 C.F.R. § 1.175)(PTO/SB/51 or 52)*
5. Original U.S. Patent
   - [X] Offer to Surrender Original Patent *(37 C.F.R. § 1.178)* *(PTO/SB/53 or PTO/SB/54)*
   - *or*
   - [ ] Ribboned Original Patent Grant
   - [ ] Affidavit / Declaration of Loss *(PTO/SB/55)*
6. Original U.S. Patent currently assigned?
   - [X] Yes [ ] No

(If Yes, check applicable box(es))

- [ ] Written Consent of all Assignees *(PTO/SB/53 or 54)*
- [X] 37 C.F.R. § 3.73(b) Statement [X] Power of Attorney

ACCOMPANYING APPLICATION PARTS

7. [X] Foreign Priority Claim *(35 U.S.C. 119)* *(if applicable)*
8. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
9. [ ] English Translation of Reissue Oath/Declaration *(if applicable)*
10. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [X] Statement filed in prior application, Status still proper and desired
11. [X] Preliminary Amendment
12. [X] Return Receipt Postcard *(MPEP 503)* *(Should be specifically itemized)*
13. [ ] Other: .....

NOTE FOR ITEMS 1 & 10: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

14. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* *or* [ ] *Correspondence address below*

Name	M. Robert Kestenbaum				
Address	11011 Bermuda Dunes NE				
City	Albuquerque	*State*	New Mexico	*Zip Code*	87111
Country	USA	*Telephone*	(505) 323-0771	*Fax*	(505) 323-0865

NAME (Print/Type)	M. Robert KEstenbaum	*Registration No. (Attorney/Agent)*	20,430
Signature	M. Robert Kest	*Date*	Sept. 16, 1999

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

PTO/SB/56 (12-97)
Approved for use through 9/30/00. OMB 0651-0033
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REISSUE APPLICATION FEE TRANSMITTAL FORM

Docket Number (Optional): TRI 42

Claims as Filed - Part 1

Claims in Patent	For	Number Filed in Reissue Application	(3) Number Extra	Small Entity Rate	Small Entity Fee		Other than a Small Entity Rate	Other than a Small Entity Fee
(A) 12	Total Claims (37 CFR 1.16(j))	(B) 19	**** 7 =	x $ 9 =	63	or	x $ ____ =	
(C) 2	Independent Claims (37 CFR 1.16(i))	(D) 3	* 1 =	x $ 39 =	39		x $ ____ =	
				Basic Fee (37 CFR 1.16(h))	$ 380			$ ____
				Total Filing Fee	$ 482		OR	$

Claims as Amended - Part 2

	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	Small Entity Fee		Other than a Small Entity Rate	Other than a Small Entity Fee
Total Claims (37 CFR 1.16(j))	***	MINUS	**	* =	x $ ____ =		or	x $ ____ =	
Independent Claims (37 CFR 1.16(i))	***	MINUS	*****	=	x $ ____ =			x $ ____ =	
				Total Additional Fee	$			OR	$

* If the entry in (D) is less than the entry in (C), Write "0" in column 3.
** If the "Highest Number of Total Claims Previously Paid For" is less than 20, Write "20" in this space.
*** After any cancelation of claims
**** If "A" is greater than 20, use (B -A); if "A" is 20 or less, use (B - 20).
***** "Highest Number of Independent Claims Previously Paid For" or Number of Independent Claims in Patent (C).

☐ Please charge Deposit Account No. _____ in the amount of _____.
A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any additional fees under 37 CFR 1.16 or 1.17 which may be required, or credit any overpayment to Deposit Account No. 11-0665.
A duplicate copy of this sheet is enclosed.

☒ A check in the amount of $ 482.00 to cover the filing / additional fee is enclosed.

09/16/99
Date

M. Robert Kestenbaum
Signature of Applicant, Attorney or Agent of Record

M. Robert Kestenbaum
Typed or printed name

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re:	Application for Reissuance of US Patent	5,667,504
	Issued	September 16, 1997
	Inventor	Baumann et al.
	Attorney Docket	(B&B) TRI 42

Assistant Commissioner for Patents
Washington, DC 20231

Preliminary Amendment

In connection with the accompanying Reissue Application, please amend the above-identified patent as follows:

In the Claims:

1. (Amended) Process for adjustment of a switchable, electromechanical flow-limiting device inside a patient's body having [at least three] multistable operating states for limited flow of liquids or gases from a medicament supply container inside a patient's body by means of a service device outside said patient's body, said flow-limiting device and said service device being spatially separated with no bodily connection between said service device and said flow-limiting device comprising:

establishing different flow rates for said liquids or gases from said medicament supply container by means of different throttle paths arranged to follow said flow-limiting device in a device that includes said flow-limiting device, and,

transmitting energy needed for adjustment of said electromechanical flow-limiting device from said service device into said device that includes said flow-limiting device,

thereby switching said flow-limiting device among said [at least three] multistable

operating states to switch said flow of said liquid or gases from said medicament supply container from one throttle path arrangement to another only during a duration of said energy transmission.

2. Process for the adjustment of a switchable flow-limiting device according to claim 1, wherein said device that includes said flow-limiting device is an infusion pump for implantation into a patient's body for treatment of the patient with medicament, said infusion pump having at least one puncture point for filling a supply container to store a selected medicament, further comprising:

transporting said selected medicament from said supply container to said flow-limiting device by means of a liquid transporting arrangement, and

introducing said selected medicament from said supply container into said patient's body by means of said throttle paths.

3. Process for the adjustment of a switchable, flow-limiting device according to claim 2, further comprising measuring filling-level values of said supply container with a sensor and storing said filling-level values intermediately in a memory in said infusion pump.

4. (Amended) Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said switchable flow-limiting device comprises a valve having at least two [three] stable positional operating states.

5. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said energy transmitting step comprises transmitting energy only intermittently.

6. (Amended) Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said switching step comprises moving a piston within said flow-limiting device between two stable end positions in an interior of said flow-limiting device [and a third stable position achieved by combination of magnetic holding force and restoring spring force].

7. Process for the adjustment of a switchable, flow-limiting device according to claim 6, further comprising retaining said switchable, flow-limiting device in said stable positions without drawing electric current.

8. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said energy transmitting step comprises transmitting said energy inductively.

9. Process for the adjustment of a switchable, flow-limiting device according to claim 1, further comprising transmitting intermediately stored data from an interior of an infusion pump that includes said flow-limiting device to said service device by means of a data transmission device having portions located in said infusion pump and in said service device.

11. (Amended) Apparatus for adjustment of the flow of liquids or gases inside a patient's body, comprising:

a device inside said patient's body including [a] an electromechanical flow-limiting device and a medicament supply container,

and a service device outside said patient's body that enables switching of said flow-limiting device,

wherein said flow-limiting device is a switchable flow-limiting device having [at least

three] multistable operating states,

said flow-limiting device and said service device being spatially separated with no bodily connection between said flow-limiting device and said service device,

a plurality of throttle paths arranged to follow said flow-limiting device in said device that includes said flow-limiting device and said medicament container, and

a device for transmitting energy needed for adjustment of said flow-limiting device from said service device to switch said flow of said liquids or gases from said medicament supply container from one throttle path arrangement to another only during the duration of energy transmission from said service device,

said flow-limiting device comprising a piston in a chamber within said flow-limiting device and an integrated leaf spring structure for mounting and guiding said piston,

said piston being stable in [three] at least two positional operating states, and

said chamber having at least one lateral intake and at least two end faces with a central opposed outlet on each of said at least two end faces.

Please add the following claims:

13. An implantable medical pump, comprising:

a fluid reservoir;

a passive regulator assembly adjustable to a plurality of flow rate settings for regulating the flow of fluid from the fluid reservoir;

an electromechanical controller for changing the passive regulator assembly from a first flow rate setting to a second flow rate setting when said electromechanical controller receives an induced voltage and in response to control signals; and

a receiver for receiving radio frequency signals operative to maintain the induced voltage in the electromechanical controller in response to received radio frequency signals.

14. The implantable medical pump according to claim 13, wherein the receiver for receiving radio frequency signals is further operative to provide control signals to the electromechanical controller in response to received radio frequency signals.

15. The implantable medical pump according to claim 14, wherein the regulator assembly for regulating the flow of fluid from the fluid reservoir comprises a valve.

16. The implantable medical pump according to claim 14, wherein the regulator assembly for regulating the flow of fluid from the fluid reservoir comprises a valve and a flow restrictor, and wherein the valve is operatively coupled to the flow restrictor.

17. The implantable medical pump according to claim 14, wherein the regulator assembly for regulating the flow of fluid from the fluid reservoir comprises a plurality of valves and a flow restrictor network which are operatively coupled.

18. The implantable medical pump according to claim 14, wherein the radio frequency signals are received from a programmer.

19. The implantable medical pump according to claim 14, further comprising a sensor for sensing, in response to a received radio frequency sense command, the amount of fluid in the fluid reservoir.

Respectfully submitted,

M. Robert Kestenbaum
Reg. No. 20,430
11011 Bermuda Dunes NE
Albuquerque, NM USA 87111
Phone (505) 323-0771
Fax (505) 323-0865

PROCESS FOR THE ADJUSTMENT OF A SWITCHABLE FLOW LIMITING APPARATUS, AND AN APPARATUS OPERATING ACCORDING TO THE PROCESS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to processes for a switchable flow-limiting apparatus for limiting the flow of liquids or gases in a patients body, and an apparatus which operates according to the process.

Such apparatuses are used for very varied applications. It is particularly difficult if these apparatuses when in use can no longer be manually adjusted without further action. Particularly for infusion equipment, it is required that the devices furthermore operate absolutely reliably, since a person's life depends on their functional capability. For this reason, the concern in what follows will primarily be with apparatuses which are suitable for use in infusion equipment. However, this is not to preclude the application of the invention to other fields of use.

2. Relevant Prior Art

Infusion systems which are implanted into the body of a patient are already known. They are used for the controlled administration of medicaments. Implantable infusion devices, also termed infusion pumps or medicament pumps, have particular uses in the following aspects of the case: spastic therapy, pain therapy, chemotherapy, and so on. They make possible a direct, continuous administration of medicament (for example, Baclofen or morphine) into the arterial or venous system, and also into the epidural or intraspinal space of the human body. The kind of medicament supply permits such a small dose (0.5–3 ml per 24 hours) that the patient's quality of life is still maintained while the organism is spared side effects which burden it, such as are known in the usual therapies (tablets, drops, injections).

Implantable infusion devices with a fixed, predetermined flow rate have the disadvantage that when the aspects of the case of the patient changes such that a greater or smaller medicament requirement is needed, after implantation of the device, a very expensive pump removal and re-implantation has to be undertaken in order to maintain the patient's quality of life.

Furthermore, it is desired in connection with certain therapies to vary the amount of the medicament which is delivered in a unit of time.

Implantable infusion devices with a battery as an energy source are partially equipped with a controllable flow rate and are electronically controlled. These infusion devices have a normal life, which is limited by the life of the energy supply, of about 36 months in the body of the patient. After that, the removal of the pump is necessary in order to renew the energy source. Thus the duration of functioning of the implant is limited to a relatively short time by the limited life of the energy storage unit (battery or accumulator). These appliances moreover have a very expensive control appliance, which is for the most part considered to be operator-unfriendly, and with which the physician can newly provide the changes and cycles of the flow rate, according to a program.

Legal determinations, for example in Germany, can however forbid a re-implantation; otherwise, a multiple use of the expensive infusion devices would be perfectly possible.

Thus at the present the target group of patients is very limited on cost grounds, and chiefly includes pain therapy in the final stages.

In an advanced version of an infusion device without an electrical energy storage unit, different throttle paths can be combined together (German Laid-Open Patent Application DE-OS 4,123,091), whereby it is possible to set different flow rates. This is achieved by means of a mechanical bistable element, which is set with a key by hand before implantation. The adjustment can also take place after implantation, by a minor operation. The element adjustments then become accessible from outside through a small cut, and the implant itself can remain in the body.

From German Laid-Open Patent Application DE-OS 3,247,232, an infusion system for the supply of medicament is known in which the implanted infusion appliance has a memory device for operating information, able to transmit the stored data to a remote measuring device outside the body of the patient who has an implanted infusion appliance. This remote measuring device and the infusion appliance both have a transmitter and a receiver, so that an instruction for a remotely controlled readiness for operation can be transmitted to the infusion appliance from an instruction transmitting device which is exterior of the body. In the system, various operating data can be interrogated from outside, and the infusion rates can be varied from outside. For this purpose, the infusion appliance has various sensors to monitor the operating data, and a pump which operates in a pulse mode.

From East German Patent DD-PS 293,055, an electromagnetically controlled bistable device is known for implantable infusion pumps which are operated by propellant gas, and which have a bistable device with opposed adjacent operating states. Energy supply here takes place inductively from outside. The bistable device then permits only the two operating states, OFF and ON.

From European Patent EP-PS 0,019,814, a control device for infusion appliances is known, in which control signals are coded in the implanted appliance housing of the infusion appliance.

From European Laid-Open Patent Application EP-OS 0,110,117, there is known an implantable microinfusion pump system, which includes a pump with pulse operation.

From European Patent EP-PS 0,031,850, there is known an implantable, magnetically controlled system for the infusion of pharmaceuticals or medicaments into a living body, with a pressure-actuated apparatus for the delivery of pharmaceuticals, and having a movable bistable element.

From European Patent EP-PS 0,039,124, an implantable infusion appliance which has a flow limiter is known.

From European Patent EP-PS 0,128,703, a micropump for implantation is known, and has an ON/OFF element as a flow controller which is normally closed and which is actuated from an external electromagnet.

SUMMARY OF THE INVENTION

The invention has as its object to provide a process for the adjustment of a switchable, flow-limiting apparatus, and an apparatus operating according to the process, the time of use of which is not limited by an electrical energy storage unit, and in which a change of the operating setting, and hence a change in the flow rate, is possible by means of the apparatus, without direct bodily contact with the apparatus.

This object is achieved by means of a service device that is spatially separated and not in bodily connection with the flow-limiting apparatus. According to the process, energy needed for adjustment of the flow-limiting device is transmitted from the service device. The flow-limiting device is

switched to adjust its operating setting only during the duration of the energy transmission.

By means of the procedure of adjustment according to the invention, an optimum safety of adjustment (particularly for infusion devices) is achieved, without any necessity for dispensing with the advantageous possibility of adjustment itself, and respectively without a direct bodily contact with the apparatus being necessary for the adjustment.

All of the advantages of the electronically controlled apparatuses are obtained, without it being possible for any inadvertent, uncontrolled adjustment of the flow rate to happen.

The range of variation which is available for the setting of the different flow rates, and the related number of required devices for limiting flow rates in a spatially limited equipment, can be optimized by multistable, flow-limiting valves.

The adjustment of the flow-limiting apparatus can be made even more secure if the external feed of energy takes place only intermittently. The feed of energy then advantageously always takes place when an adjustment of the flow rate limiting apparatus is to be undertaken.

When the setting of different flow rates (e.g., for medicaments from a supply container) takes place by means of different throttle paths arranged following the flow-limiting apparatus, the flow rate can no longer be changed after a setting of the flow-limiting apparatus, until the next adjustment of the flow-limiting apparatus. This procedure thus provides increased security in operation. This is of great importance, particularly for infusion devices.

The multistable, flow-limiting apparatus can advantageously be realized in that a piston is moved in the interior of the flow-limiting apparatus, that the piston has two stable end positions, and that a third positionally stable state of the piston is attained by the combination of magnetic holding force and a restoring spring force.

It is very advantageous for operating security and life if the flow-limiting apparatus remains in its stable positions without drawing current.

It is advantageous if the external feed of energy takes place inductively. This energy feed is cost-favorable and requires relatively little space for its realization. This is of particular importance for infusion devices.

It is very advantageous if data transmission exists, into and out of the device with the flow-limiting apparatus. For this purpose, a data transmission device must be provided in the device and in an external service appliance. This makes possible a data transmission from within the device, e.g., of data intermediately stored in an EEPROM, to the service appliance. However, other data, which are determined outside the device with the flow-limiting apparatus are passed on to the device, also to be transmitted to the exterior. This means, for an implanted infusion device, that the data from the interior of the patient's body can be transmitted outside the patient's body.

It is advantageous, in the us of the flow-limiting apparatus in an infusion device, if the state of filling of the supply contained in the infusion device is measured and these data are intermediately stored in the infusion unit in an electronic memory. EEPROMs are particularly suitable as electronic memories, since they require no energy to maintain the memory contents.

In the infusion device, a pressurized gas reservoir is particularly suitable as the liquid forwarding device, and exerts a pressure on the supply container in the direction of

the flow-limiting apparatus. This pressurized gas reservoir has the advantage of very high operating security with a relatively small space requirement.

Advantageous arrangements are described in the claims and especially in the description of the drawings.

It is also very advantageous if the device with the flow-limiting apparatus has an electronic circuit. This serves, in particular, for data transmission, if necessary for data determination, if necessary for data storage, and if necessary also for the preprocessing of the data which have been determined.

Advantageous arrangements of the electronic circuit are described in the claims and especially in the description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be explained in more detail below, with reference to the drawings, in connection with which further features of importance to the invention will be explained. The use of the flow-limiting apparatus in an infusion device will be described there by way of example, although the invention is not to be limited to the use of the apparatus in such a device.

In the Figures:

FIG. 1 shows an infusion device with a flow-limiting apparatus according to the invention;

FIG. 2 shows a section through the flow-limiting apparatus;

FIG. 3 shows a perspective view of the section through the apparatus as shown in FIG. 2;

FIG. 4 shows the spring element from the apparatus, in top view;

FIG. 5 shows the spring element of FIG. 4, represented in perspective; and

FIG. 6 shows a diagram of the components contained in the service appliance and in the infusion device.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The infusion pump (1) shown in FIG. 1 has a septum (2), through which a medicament can be filled into the supply container (3) with a hypodermic needle (not shown in the Figure) through the abdominal wall, when the infusion pump (1) has been implanted into the body of a patient. The supply container (3), which acts as the medicament chamber, is bounded by a bellows (4) which expands on filling. This bellows (4) consists of titanium. The nearly constant excess pressure of the propellant gas in the pressurized gas reservoir (5) exerts a pressure on this bellows (4), leading in the course of time to an emptying of the medicament from the supply container (3). The pressurized gas reservoir (5) is bounded laterally by a partition (9), and is dimensioned such that the gas exerts a nearly constant pressure on the supply container (3) for the whole time while this is being emptied.

A sewing eyelet (10) is fitted laterally on the housing of the infusion pump (1); at it, the infusion pump (1) is sewn firmly to the surrounding tissue, so that during the duration of the implantation the infusion pump (1) does not change its position too much and thereby cause pain to the wearer.

The throttle paths (7: 7.11; 7.12; 7.21; 7.22) limit the quantity of medicament which can be delivered per unit time from the supply container. These throttle paths (7) begin behind the valve (6: 6.1; 6.2), which opens or closes the throttle paths (7) for medicament flow. The throttle paths (7)

all end in a bolus septum (11) and have an outlet there via a catheter (12) into the interior of the body. The physician can also inject directly into this bolus septum (11), in order to administer an additional dose of medicament to the wearer of the infusion pump (1).

The septum (2) and the bolus septum (11) project out of the housing of the infusion pump (1), so that the physician can feel the two septa (2, 11) when searching for them.

In the septum (2), a needle stop (8) ensures that the injection needle (not shown in the drawing) is not damaged while the supply container (3) is being filled.

The outlet of the medicament from the infusion pump (1) takes place through the throttle paths (7) which are connected following the valve (6), so that a constant flow rate is reached. An inlet from the supply container (3) goes into each of the two valves (6.1 and 6.2), and two throttle paths (7.11 and 7.12; 7.21 and 7.22) lead out from each valve (6.1 and 6.2). The flow rate then depends on the gas pressure and in addition primarily on the length of the throttle paths (7) and on their capillary diameter.

If several throttle paths (7) are used, different flow rates can be achieved by the parallel and/or serial connection of various throttle paths (7). The changeover then takes place by means of a tri-stable electromechanical microvalve (6). This valve (6) is explained in more detail in the following FIGS. 2, 3 and 4.

In FIG. 2 there is shown a section through a electromechanical valve (15), having three stable operating positions and in FIG. 3, a view of a section through the valve (15). The piston (16) consists of a permanent magnet material (e.g., Vacodym), and is encapsulated with a material (e.g., titanium) of the encapsulation (23, 24) which is compatible (i.e., not reacting) with the medicaments used. The fastening of the piston (16) consists of a spring element (19) (see FIGS. 4 and 5).

The spring element (19) of FIG. 2 centers, and likewise guides, the piston (16) within the valve chamber (17).

The leaf springs of FIG. 5, which run in two planes (18*a*, 18*b*) exert a prestress which is respectively directed towards the center and which makes possible a stable middle position of the piston (16). The prestresses are produced by the deformation of the spring element (19) during mounting. The mounting ring (22) spreads a portion of the spring element (21*a*, *b* and *c*), thus producing a force component on the piston (16) in the positive Z-direction (up direction according to Cartesian coordinates). The leaf springs (20*a*, *b* and *c*) are prestressed inwards by the encapsulation (23, 24) of the piston as in FIG. 2, so that a force is produced in the negative Z-direction (down direction according to Cartesian coordinates). On motion of the piston in the negative or positive Z-direction, dependent on direction, respective leaf springs of the one plane are relieved of stress and in the other plane are further stressed, or vice versa.

The valve chamber (17) has a lateral inlet (25) and, arranged on the end faces, two opposed, central outlets (30*a*, 30*b*), to each of which is fitted a respective capillary connection (26*a*, 26*b*) to the throttle paths (7).

A respective electromagnet (27*a*, 27*b*), with a coil former (28*a*, 28*b*) of low retentivity magnetic material, is seated on each end face of the valve chamber (15). By correct poling of the two coils (29*a*, 29*b*), the permanent magnetic piston (16) can be moved out of its middle position which is defined by the leaf springs (20*a*, *b*, *c*; 21*a*, *b*, *c*) towards the +Z direction or the −Z direction. When the piston (16) has been completely pulled into a position at one end of its path, one of the two outlets (30*a*, 30*b*) is closed. After the current

is switched off, this position of the valve (15) is still maintained. The required holding forces are produced by the permanent magnet piston (16) and the magnetization which it produces of the respective coil formers (28*a*, 28*b*) of the electromagnets (27*a*, 27*b*). The dimensions are to be made such that the permanent magnetic holding force is greater than the restoring force of the leaf springs (20*a*, *b*, *c*; 21*a*, *b*, *c*).

The position at any given time of the valve (15) is determined by sensors (31*a*, 31*b*) which are sensitive to magnetic fields, and which are built in on the end face on the side of the electromagnets (27*a*, 27*b*) facing the valve chamber (17). A maximum field strength is then set in the end positions for the sensor concerned (31*a*, 31*b*).

In the middle position (M) defined by the leaf springs (20*a*, *b*, *c*; 21*a*, *b*, *c*), the field strength is about equal for both end position sensors (31*a*, 31*b*). This middle position can be achieved by a dynamically controlled adjustment of the valve (15). It is possible to bring the piston (16) into the middle position by means of the built-in sensors (31*a*, 31*b*) by means of a suitable control electronics, (e.g., a PI controller, in which the flux through both magnetic field sensors is equal in the middle position: $\Phi_1=\Phi_2 \rightarrow \Phi_1-\Phi_2=0$ (reference value for the controller)). After the electromagnets (27*a*, 27*b*) are switched off, this state is still maintained, since the spring force dominates the magnetic attractive forces, which then scarcely differ.

The piston (16) can be directed into its stable positions by the orientation of the current through the coils (29*a*, 29*b*) of the two electromagnets (27*a*, 27*b*). Here at any given time one of the two capillary connections (26*a*, 26*b*) at the two outlets (30*a*, 30*b*) is closed or opened, in an end position of the piston (16). In the middle position, both capillary connections (26*a*, 26*b*) are opened.

The extracorporeal service appliance (32) and the implanted infusion device (33) are shown schematically in FIG. 6.

The infusion device (33) has an electronic control device (34) which controls all activities in the infusion device (33). This control device (34) consists essentially of an EEPROM (35), a single chip computer (36), a serial interface (37) (a parallel interface would also be conceivable, but without advantage), and a port (38) to which various drivers and sensors can be connected.

The serial interface (37) is connected to a modulator/demodulator (39) for the absorption telemetry (40). This absorption telemetry (40) consists of a LF/RF converter and serves for communication between the infusion device (33) and the extracorporeal service appliance (32). The same antenna serves both for energy transmission and also for bidirectional data transmission.

There is contained in the service appliance (32) a coil (32*a*) via which energy can be inductively transmitted into the infusion device (33). The transmitted energy is used to operate the single chip computer (36), the sensors, (43, 44) the driver (45) and the valve (42). Energy coupling takes place only in the presence of the extracorporeal service appliance (32).

Two sensors (43, 44) are connected to the port (38) of the single chip computer (36) and ascertain the position of the valve (42). The mode of operation of these sensors (43, 44) has already been explained in connection with FIGS. 2, 3 and 4.

Moreover a driver (45) for a valve changeover unit (46) is connected to the port (38). The position of the valve (42) can thus be changed by means of a corresponding

instruction, received from the service appliance (32) by the receiver in the absorption telemetry (40) and transmitted via the serial interface (37) to the single chip computer (36). The corresponding control characteristic is produced by the single chip computer (36) and correspondingly acts on the changeover unit (46).

Furthermore a filling level sensor (47) is connected to the port (38) of the single chip computer (36), and transmits to the single chip computer (36) a message concerning the level, i.e., concerning the quantity of medicament which is still present in the supply container (48). The single chip computer (36) calculates therefrom the infusion time still available and tests whether the amount of flow agrees with the values which have been set. Additionally, the physician can add fluid into the supply container 48 via a needle 71.

A duct (49) leads from the supply container (48) to the valve (42). The supply container (48) is constructed as a bellows and is constantly under the pressure of a pressurized gas reservoir (50). The pressure exerted by the pressurized gas reservoir (50) on the supply container (48) drives the medicament contained in this in the direction towards the valve (42).

Two throttle paths (51, 52) lead from the valve (42). The throttle paths (51, 52) ensure that the supply container (48) empties only in a controlled manner. They consist of capillaries, and the quantity of liquid flowing through them per hour is dependent on the pressure difference over the throttle paths (51, 52), on their capillary length, and on the capillary diameter of the individual throttle paths (51, 52); this diameter can be different for each throttle path (51, 52). The valve (42) opens both throttle paths (51, 52) or only one. As long as the position of the valve (42) is not changed, the quantity of liquid delivered per hour remains constant.

The two throttle paths (51, 52) end in the bolus (53), at the outlet of which is located a catheter (54) into the interior of the body of the wearer of the implanted infusion device (33). The physician can also inject a medicament directly into the bolus (53) with an injection needle (55).

The service appliance (32) has a transformer (41) as a component of the absorption telemetry (40) for the inductive transmission of energy to the infusion device (33). This transformer (41) is supplied by a battery (61). The battery (61) is also connected to a microcontroller 56 (36).

An operator, who will normally be a physician, can by means of a keyboard (57) or by means of function keys (58) interrogate from the infusion device (33) the operating data determined by the single chip computer (36) in the infusion device (33), or can initiate an adjustment of the valve (42) in the infusion device (33). For this purpose, the service appliance (32) has a data communication device (59), which consists of a modulator and demodulator for the absorption telemetry (40). All the operating parameters transmitted from the infusion device (33), and also the instructions sent to it, can be displayed on a LCD display (60).

The service appliance (32) thus performs two tasks. Firstly, energy is inductively transmitted from the service appliance (32) into the implanted infusion device (33) when the service appliance (32) is brought into the vicinity of the infusion device (33) (abdominal wall). During the transmission of energy, the valve (42) can be controlled from the service appliance (32) by means of an absorption telemetry which is located both in the service appliance (32) and in the infusion device (33). A single chip computer (36) is mounted in the infusion device (33), effects the communication with the service appliance (32), and can change over as prescribed, and control the functioning of, the internal valve

(42) having three stable operating positions located in the infusion device (33).

No electrical energy is stored in the infusion device (33) in order to change over the valve (42). In order to change over the valve (42) contained in the infusion device (33), energy has to be transmitted inductively into the infusion device (33).

If the service device (32) is moved away, the inductive coupling is broken and the implanted infusion device (33) becomes without current, so that an adjustment of the valve (42) cannot take place. The flow rate which has been set is however still maintained, since the valve or valves (42), connected in series or in parallel, remain in their stable operating position(s). The possibilities of variation of the flow rate can thus be greatly increased by the use of several valves (42).

When the infusion device (33) is activated (i.e., energy is transmitted from the extracorporeal service device (32)), the filling level can be measured by means of a sensor (47). From the level and the flow rate which has been set, the remaining time to the next filling can be indicated for the patient on the display (60) of the service appliance (32). The monitoring of the flow rate can then advantageously be determined by means of stored level values. EEPROMs which permanently store the level values are particularly suitable here.

From the adjustability and the filling level measurement, and the possibilities resulting from these, a flexibility results which was otherwise reserved to the electronic infusion devices, but without having to accept the disadvantage of the greatly limited life due to battery operation.

An absolute insensitivity of the final electrically controlled valve (42) to interference from external interfering effects is achieved by the realization of the energy coupling according to the invention. In contrast to this, in infusion devices in which the adjustment of the valve takes place by means of the current of an electrical storage device (i.e., with a permanent electrical supply, e.g., a battery), there is always the danger that these infusion devices are reprogrammed by interference effects from the exterior.

In the infusion device (33) according to the invention, a doubled security is achieved. In the first place, the infusion device (33) is passive in the normal state. Apart from this, data transmission is effected, for security reasons, by means of absorption telemetry. Additional security against interfering pulses is realized by an additional coding of the data and instructions to be transmitted. Moreover, the absorption telemetry is only effective at close range.

We claim:

1. Process for adjustment of a switchable, flow-limiting device inside a patient's body having at least three stable operating states for limited flow of liquids or gases by means of a service device outside said patient's body, said flow-limiting device and said service device being spatially separated with no bodily connection between said service device and said flow-limiting device comprising:

establishing different flow rates for said liquids or gases by means of different throttle paths arranged to follow said flow-limiting device in a device that includes said flow-limiting device, and,

transmitting energy needed for adjustment of said flow-limiting device from said service device into said device that includes said flow-limiting device,

thereby switching said flow-limiting device among said at least three stable operating states to switch said flow of said liquids or gases from one throttle path arrangement to another only during a duration of said energy transmission.

2. Process for the adjustment of a switchable flow-limiting device according to claim 1, wherein said device that includes said flow-limiting device is an infusion pump for implantation into a patient's body for treatment of the patient with medicament, said infusion pump having at least one puncture point for filling a supply container to store a selected medicament, further comprising:

transporting said selected medicament from said supply container to said flow-limiting device by means of a liquid transporting arrangement, and

introducing said selected medicament from said supply container into said patient's body by means of said throttle paths.

3. Process for the adjustment of a switchable, flow-limiting device according to claim 2, further comprising measuring filling-level values of said supply container with a sensor and storing said filling-level values intermediately in a memory in said infusion pump.

4. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said switchable flow-limiting device comprises a valve having at least three stable positional operating states.

5. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said energy transmitting step comprises transmitting energy only intermittently.

6. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said switching step comprises moving a piston within said flow-limiting device between two stable end positions in an interior of said flow-limiting device and a third stable position achieved by combination of magnetic holding force and restoring spring force.

7. Process for the adjustment of a switchable, flow-limiting device according to claim 6, further comprising retaining said switchable, flow-limiting device in said stable positions without drawing electric current.

8. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said energy transmitting step comprises transmitting said energy inductively.

9. Process for the adjustment of a switchable, flow-limiting device according to claim 1, further comprising transmitting intermediately stored data from an interior of an infusion pump that includes said flow-limiting device to said

service device by means of a data transmission device having portions located in said infusion pump and in said service device.

10. Process for the adjustment of a switchable, flow-limiting device according to claim 1, wherein said energy transmitting step comprises transmitting energy inductively by means of absorption telemetry.

11. Apparatus for adjustment of the flow of liquids or gases inside a patient's body, comprising:

a device inside said patient's body including a flow-limiting device,

and a service device outside said patient's body that enables switching of said flow-limiting device,

wherein said flow-limiting device is a switchable flow-limiting device having at least three stable operating states,

said flow-limiting device and said service device being spatially separated with no bodily connection between said flow-limiting device and said service device,

a plurality of throttle paths arranged to follow said flow-limiting device in said device that includes said flow-limiting device, and

a device for transmitting energy needed for adjustment of said flow-limiting device from said service device to switch said flow of said liquids or gases from one throttle path arrangement to another only during the duration of energy transmission from said service device,

said flow-limiting device comprising a piston in a chamber within said flow-limiting device and an integrated leaf spring structure for mounting and guiding said piston,

said piston being stable in three positional operating states, and

said chamber having at least one lateral intake and at least two end faces with a central opposed outlet on each of said at least two end faces.

12. Apparatus according to claim 11, wherein said piston comprises a permanent magnet further comprising a separately acuatable electromagnet having a coil former on each side of said at least two end faces.

* * * * *

Attachment B

Claims 1 and 11 specify a flow-limiting device inside a patient's body having at least three stable operating states. As a result of this error the patentees claim less than they had a right to claim.

Claim 1 and 11 are amended in this Reissue Application to specify an electromechanical flow limiting device that limits flow of liquids or gases from a medicament supply container inside a patient's body having multistable operating states, rather than at least three stable operating states.

Claims 4 and 11 have been amended to recite that the flow limiting device comprises a valve (a piston in claim 11) having at least two --rather than three-- positional operating states. A corresponding change is made in claim 6.

The claims as amended are supported in the specification and drawings, for example, in column 3, lines 13-17, lines 32-37; Figures 2 and the discussion in column 6, lines 28-34; Figure 3 and the discussion in column 7, lines 23-33.

The claims also claim less than the patentee's have a right to claim by failing to recite:

An implantable medical pump comprising a fluid reservoir; a passive regulator assembly adjustable to a plurality of flow rate settings for regulating the flow of fluid from the fluid reservoir; an electromechanical controller for changing the passive regulator assembly from a first flow rate setting to a second flow rate setting when the electromechanical controller receives an induced voltage and in response to control signals; and a receiver for receiving radio frequency signals operative to maintain the

induced voltage in the electromechanical controller in response to received radio frequency signals.

These features are supported in the specification and drawings. Figure 1 shows an implantable pump (1) comprising a fluid reservoir (3), a passive regulator assembly (6, 7) adjustable to a plurality of flow rate settings for regulating the flow of fluid from the fluid reservoir, an electromechanical controller (15 in Figure 2) for changing the passive regulator assembly from a first flow rate setting to a second flow rate setting when the electromechanical controller receives an induced voltage and in response to control signals, and a receiver (34-42 in Figure 6) for receiving radio frequency signals operative to maintain the induced voltage in the electromechanical controller in response to received radio frequency signals.

PTO/SB/52 (12-97)
Approved for use through 9/30/00. OMB 0651-0033
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REISSUE APPLICATION DECLARATION BY THE ASSIGNEE	Docket Number (Optional) TRI 42

I hereby declare that:
My residence, post office address and citizenship are stated below next to my name.
I am authorized to act on behalf of the following company: Tricumed GmbH
and the title of my position with said company is: Managing Director
The entire title to the patent identified below is vested in said company.

Name of Patentee(s): See Attachment A

Patent Number	Date Patent Issued
5,667,504	September 16, 1997

Title of Invention: Process for the Adjustment of a Switchable Flow Limiting Apparatus, and an Apparatus Operating According to the Process

I believe said patentee(s) to be the original, first and sole or joint inventor(s) of the subject matter which is described and claimed in said patent, for which a reissue patent is sought on the invention entitled Process for the Adjustment of a Switchable Flow Limiting Apparatus, and an Apparatus Operating According to the Process
the specification of which

- [X] is attached hereto.
- [ ] was filed on _____ as reissue application number ___/_____ and was amended on _____ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

- [ ] by reason of a defective specification or drawing.
- [X] by reason of the patentee claiming more or less than he had the right to claim in the patent.
- [ ] by reason of other errors.

At least one error upon which reissue is based is described as follows:

See Attachment B

PTO/SB/52 (12-97)
Approved for use through 9/30/00. OMB 0651-0033
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

(REISSUE APPLICATION DECLARATION BY THE ASSIGNEE, page 2)

Docket Number (Optional): TRI 42

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant.

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Name(s)	Registration Number
M. Robert Kestenbaum	20,430

Correspondence Address: Direct all communications about the application to:

☐ Customer Number [ ] *Type Customer Number here* → *Place Customer Number Bar Code Label here*

OR

☒ Firm or Individual Name	M. Robert Kestenbaum				
Address	11011 Bermuda Dunes NE				
Address					
City	Albuquerque	State	NM	ZIP	87111
Country	USA				
Telephone	(505) 323-0771	Fax	(505) 323-0865		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Full name of person signing (given name, family name): Karl-Heinz Otto

Signature: Karl-Heinz Otto		Date: 14th of September 1999	
Residence: Kiel	Kiel, Germany	Citizenship: German	German
Post Office Address: Rontgenstr, 7a	DE24143 Kiel, Germany		

Attachment A

Hans Baumann, Karl-Heinz Otto, Kai-Jurgen Hinrichs, Wolfgang Graczyk, Jorg-Roger Peters

PTO/SB/96 (2-98)
Approved for use through 09/30/2000. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
he Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(b)

pplicant: Tricumed Mediz intechnik GmbH

pplication No.: 321,638 Filed: October 11, 1994

Entitled: Process for the Adjustment of a Switchable Flow Limiting Apparatus, and an Apparatus Operating According to the Process

Tricumed Medizintechnik GmbH, a corporation of Germany

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

tates that it is:

. [X] the assignee of the entire right, title, and interest; or

. [ ] an assignee of an undivided part interest

the patent application identified above by virtue of either:

. [ ] An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

. [X] A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: Inventors To: Carl Zeiss Stiftung
   The document was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: Carl Zeiss Stiftung To: Tricumed Medizintechnik GmbH
   The document was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
   The document was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

] Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.

Sept. 14th 1999
Date

Karl-Heinz Otto
Signature

Karl-HEINZ OTTO
Typed or printed name

MANAGING DIRECTOR
Title

Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comment amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/54 (12-97)
Approved for use through 9/30/00. OMB 0651-0033
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REISSUE APPLICATION BY THE ASSIGNEE, OFFER TO SURRENDER PATENT	Docket Number (Optional) TRI 42

This is part of the application for a reissue patent based on the original patent identified below.

Name of Patentee(s): See Attachment A

Patent Number	Date Patent Issued
5,667,504	September 16, 1997

Title of Invention: Process for the Adjustment of a Switchable Flow Limiting Apparatus, and an Apparatus Operating According to the Process

Tricumed Medizintechnik GmbH is the assignee of the entire interest in the original patent.

I offer to surrender the original patent.

[X] A certificate under 37 CFR 3.73(b) is attached.

I am authorized to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this declaration is directed.

Name of assignee: Tricumed Medizintechnik GmbH

Signature of person signing for assignee	Date
Karl-Heinz Otto	September 14th 1999

Typed or printed name and title of person signing for assignee: Karl-Heinz Otto, Managing Director

Burden Hour Statement: This form is estimated to take 0.1 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Attachment A

Hans Baumann, Karl-Heinz Otto, Kai-Jurgen Hinrichs, Wolfgang Graczyk, Jorg-Roger Peters

FIG. 1

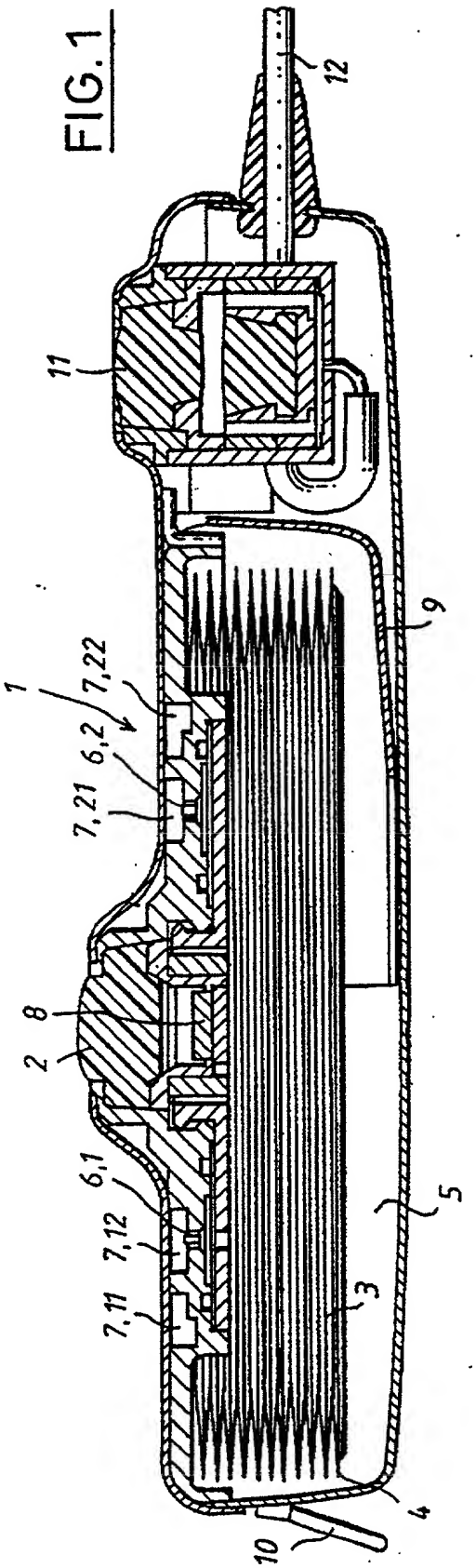


FIG. 3

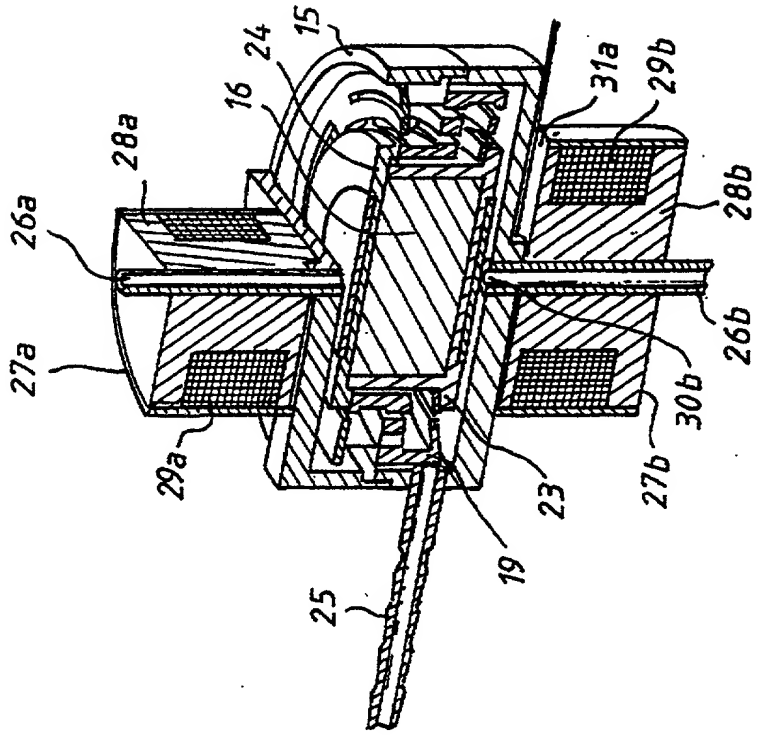
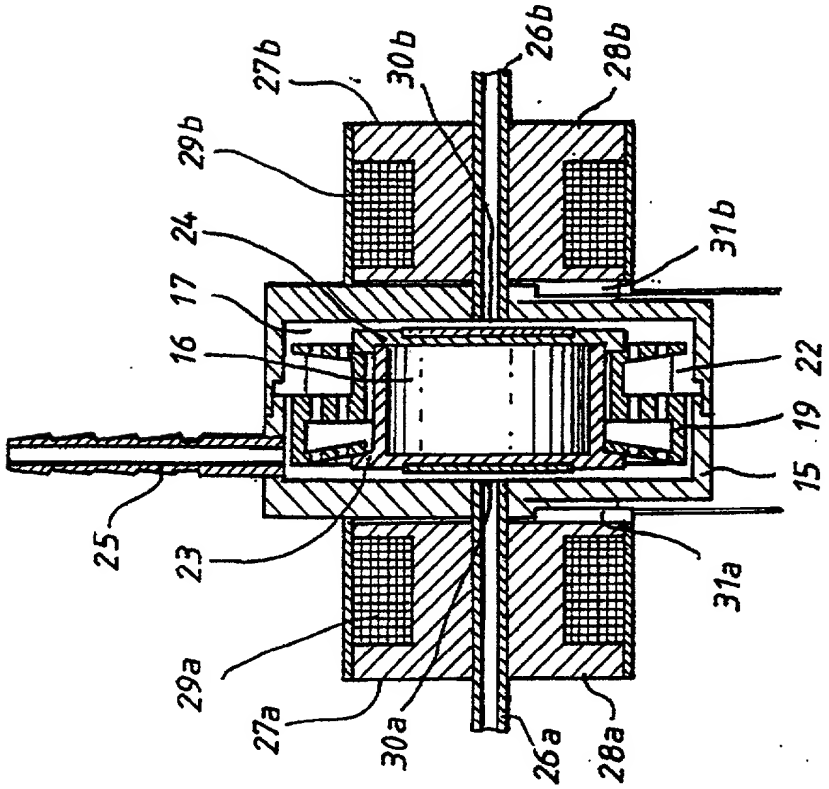

15
24
16
28a
26a
27a
29a
25
19
23
27b
30b
26b
28b
29b
31a

FIG. 2


27b
30b
26b
28b
29b
24
31b
17
16
22
19
15
25
23
31a
29a
27a
30a
26a
28a

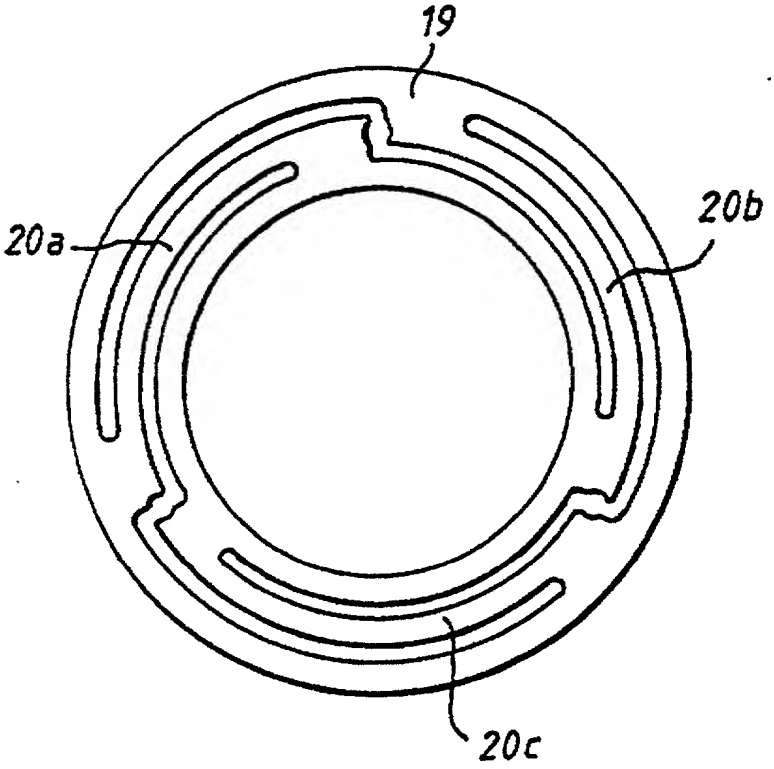


FIG. 4

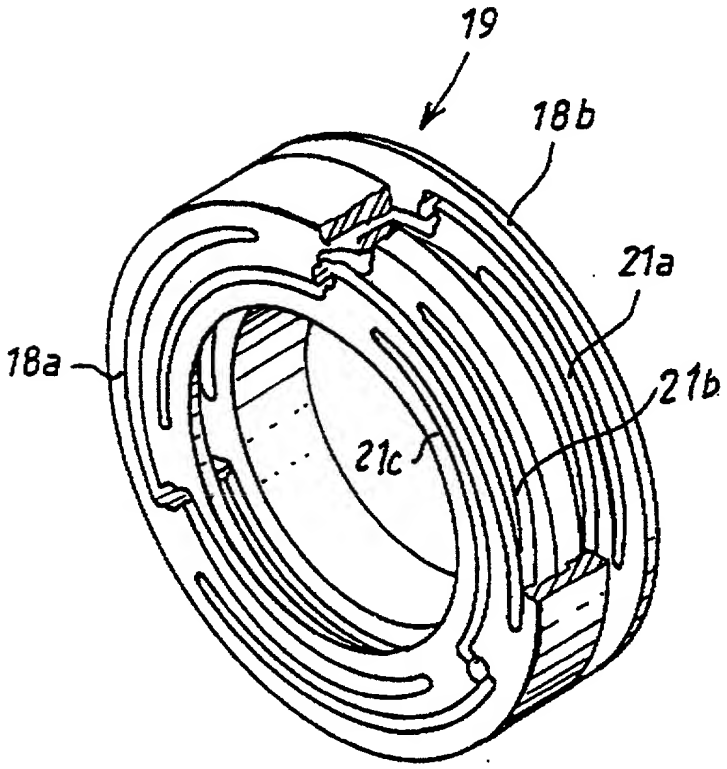


FIG. 5

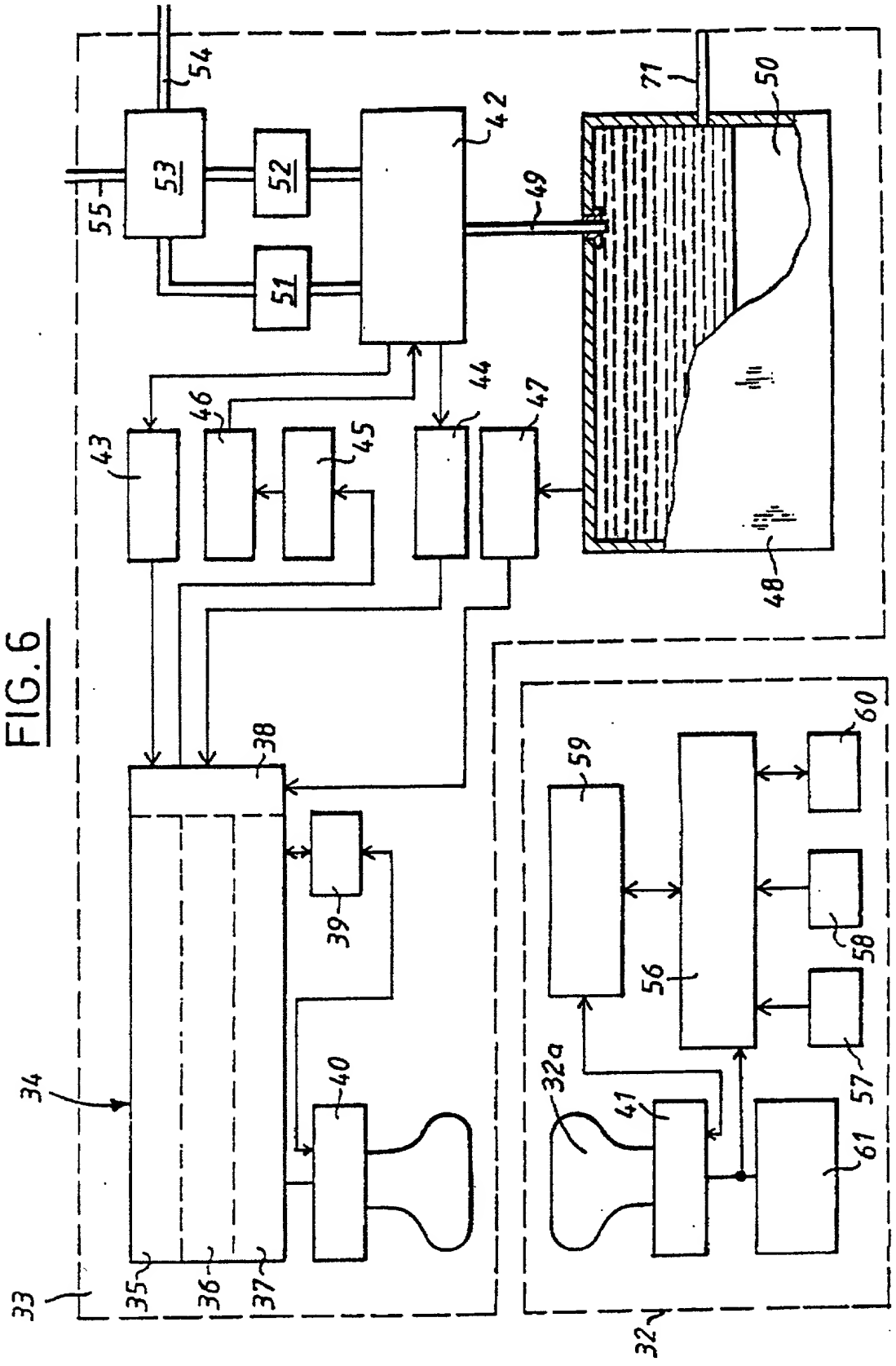

54
53
52
51
55
42
49
71
50
48
43
46
45
44
47
38
39
40
34
33
35
36
37
59
60
56
58
57
32a
41
61
32

FIG. 6